ORALS

TCT-18

6-month angiographic and 18-month clinical results of the multicenter randomized DEBIUT (Drug Eluting Balloon In BIfUrcations Trial)

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Background: Percutaneous treatment of coronary bifurcation lesions remains hampered by suboptimal results, mainly in the side branch (SB), even with the use of drug-eluting stents (DES). Drug-eluting balloons (DEB) could provide an attractive alternative to treat bifurcations in combination with a provisional T-stenting technique in order to minimize SB restenosis. We compared angiographic and clinical outcomes of a provisional T-stenting technique with the first generation DIOR DEB plus bare metal stent (BMS) versus BMS versus paclitaxel DES.
Methods: In this randomized, international multicenter, single-blinded 3-arm study, 117 patients with coronary bifurcation lesions underwent treatment with: A) DEB in both main branch (MB) and SB and BMS in MB; B) BMS in MB and regular balloon angioplasty in SB; or C) paclitaxel DES in MB and regular balloon in SB. All patients underwent provisional T-stenting with an identical stent platform in the MB. Paclitaxel was the drug for elution in groups A and C. This abstract presents the 18-month major adverse cardiac events (MACE: death, myocardial infarction, target vessel revascularization (TLR)) and 6-month angiographic results.
Results: In-hospital 8 MACE were reported, all were peri-procedural myocardial infarctions (MI); 3 (7.5%), 2 (5.4%), and 3 (7.5%) in groups A, B, and C respectively. Between discharge and 18-month follow-up results were: 1 (2.5%) cardiac death in group A due to a nontarget vessel related MI. Furthermore, 1 (2.5%) MI due to a stent thrombosis with consecutively a TLR was reported in group C. Total TLR rate at 18-month was 8 (20%), 10 (27%), and 6 (15%) in groups A, B, and C respectively. The cumulative MACE rate at 18-month was 22.5%, 29.7%, and 17.5% (p=0.47), and the 6-month angiographic binary restenosis rates per bifurcation were 24.2%, 28.6%, and 15% in groups A, B, and C respectively.
Conclusion: Pre-treatment of both MB and SB with the first generation DIOR DEB failed to show 6-month angiographic and 18-month clinical superiority over BMS. Moreover DES showed superior angiographic results than DEB and BMS.

TCT-19

A temporal assessment of drug distribution following local balloon delivery of nanoparticle sirolimus

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Background: The aim of the present study was to evaluate the temporal arterial distribution of a novel nano particle sirolimus (nSRL) delivered locally using an angioplasty balloon catheter in a rabbit ilio-femoral artery model.
Methods: The fluorescent dye 5-DTAF (Molecular Probes) was used to label nSRL where 180 µg of drug was then spray-coated onto 3 x 15 mm balloon catheters (Magic Touch, Concept Medical Inc., Twinsburg, OH). Bilateral ilio-femoral rabbit arteries pre-injured with a 3F Fogarty catheter were treated with nSRL by 60 seconds inflation of the balloon catheter at nominal pressure and harvested at 1, 24 hours and 3, 7 days and assessed using laser confocal scanning microscopy.
Results: Confocal examination showed DTAF-nSRL as a solid to diffuse bright green signal admixed with dark non-fluorescent areas (Fig. 1A). For arteries examined en face, DTAF-signal was viewed as solid to more diffuse weaker fluorescence not to exceed an estimated 25% to 35% of the luminal surface at 1 and 24-hours. At 3- and 7-days, the distribution of signal was markedly less. Histologic cross-sections examined at 1 hr post-treatment showed a strong accumulation of DTAF-nSRL localized to the IEL surface not exceeding 70% of the vessel circumference (Fig. 1B). By 24 and 72 hours however, the DTAF label was observed as a strong to faint punctate fluorescence associated with the IEL and upper medial layer (Fig. 1C). At 7-days, the pattern of DTAF was identified as a moderate to weak punctate fluorescence widely distributed throughout the medial wall with rare particulate in the adventitia.

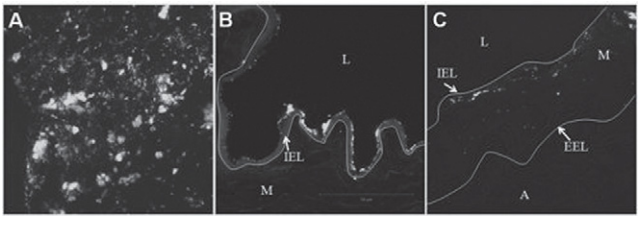

Figure 1. Representative confocal images.

Conclusion: The present study for the first time provides a visual assessment of the distribution of a novel nano carrier sirolimus when delivered locally to the arterial wall in vivo using a balloon catheter.

TCT-20

Pathologic Features of Everolimus- versus Sirolimus- and Paclitaxel- Eluting Stents in Human Coronary Arteries

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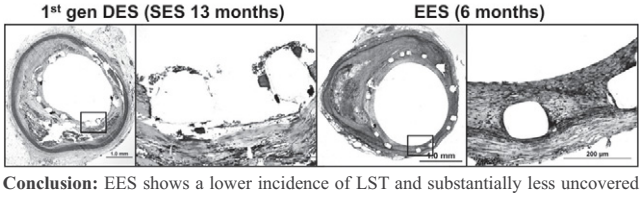
Background: Previous pathologic studies in 1st-generation drug-eluting stents (1st-gen DES; sirolimus- [SES] and paclitaxel- [PES]) have demonstrated that delayed arterial healing is accompanied by poor endothelialization as the primary substrate underlying late stent thrombosis (LST). Several clinical studies have reported that 2nd-generation everolimus-eluting stent (EES) shows a lower incidence of LST than 1st-gen DES. Little is known about the pathologic findings of EES in human coronary arteries.
Methods: From our stent registry, a total of 111 autopsy cases to include 155 DES lesions (1st-gen DES=136 [61 SES, 75 PES] and EES=19) with duration of implant >30 days and ≤2 years were examined. Histomorphometry was performed on EES vs. 1st-gen DES where endothelial strut coverage, fibrin deposition, and inflammatory response were assessed.
Results: Age, sex, risk factors, and duration of implant (1st-gen DES=211 [91-383] vs. EES=180 [151-360] days, p=0.64) were similar between 2 groups. LST was more frequent in 1st-gen DES than in EES (25.7% vs. 5.3%, p=0.04). Only 1 lesion with LST in EES was a device implanted over an underlying PES. The results of histomorphometry are shown in Table. The percent of uncovered struts was significantly lower in EES, while mean neointimal thickness did not differ between the groups. Moreover, inflammation and fibrin deposition were significantly less in EES as compared to 1st-gen DES.

Morphometric Analysis of EES vs. 1st-gen DES

	1st-gen DES (n=136)	EES (n=19)	p value
Uncovered struts (%)	20.0 (6.7, 50.0)	2.6 (0, 6.3)	0.002
Mean neointimal thickness (mm)	0.11 (0.05, 0.18)	0.17 (0.04, 0.30)	0.363
Inflammation score	1.0 (0.5, 1.5)	0.4 (0, 0.8)	0.013
Struts with fibrin (%)	48 (21, 65)	18 (0, 35)	<0.001
Maximum number of eosinophils per strut	4.1 ± 11.1	1.6 ± 3.6	0.332

Values are expressed as median (interquartile range) or mean ± SD.



Conclusion: EES shows a lower incidence of LST and substantially less uncovered struts with similar neointimal thickness, less inflammation, and less fibrin deposition as compared to 1st-gen DES in humans. These findings are consistent with greater clinical safety of EES.

Drug-Eluting Stents I

Room 125

Tuesday, November 8, 2011, 10:15 am - 12:25 pm

(Abstract nos 21 - 30)

TCT-21

Biodegradable Polymer-Coated Sirolimus-Eluting Stent Implantation in Acute Myocardial Infarction

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Background: The present study sought to evaluate the safety and effectiveness of Excel in acute myocardial infarction with 6-month dual antiplatelet therapy in daily practice.
Methods: Since November 10, 2006, a policy of routine Excel stents implantation has been instituted in 59 centers from 4 countries. During 6 months of enrollment, 760 patients with acute myocardial infarction underwent percutaneous recanalization and Excel stents implantation. Six-month angiographic follow-up was scheduled per protocol.

Results: Overall, 1082 target lesions were identified. The target lesions were A type in 111 cases (10.3%), B1 in 201 (18.6%), B2 in 252 (23.3%), and C in 518 (47.9%). Complete follow-up was available for 99.3% of the patients at 180 days, 99.1% at 360 days, and 99.1% at 540 days. A total of 17 deaths occurred during the 180 days (2.3%), 25 deaths occurred during the 360 days, and 27 deaths occurred during the 540 days. In none of these cases, death occurred as an unexpected, sudden episode that could be attributable to stent thrombosis. no patient had recurrent myocardial infarction, and there were no additional reinterventions. Also, 5 thrombosis events by ARC definition at 18-months were documented. The average duration of clopidogrel treatment was 180 days. The cumulative rates of major adverse cardiac events were 2.0% at 180 days, 3.9% at 1 year, and 4.2% at 18 months. Overall rate of stent thrombosis was 0.87% at 18 months. The rates of acute, subacute, late, and very late stent thrombosis were 0.1%, 0.38%, 0.34%, and 0.05%, respectively. Angiographic follow-up, performed in 974 (31.6%) lesions from 653 patients (31.7%), revealed a mean in-stent late lumen loss of 0.21 ± 0.39 mm. Binary restenosis rates were 3.8% in-stent and 6.7% in-segment.
Conclusion: This multicenter registry documents satisfactory safety and efficacy profiles, as evidenced by low rates of major adverse cardiac events and stent thrombosis up to 18 months, for the Excel biodegradable polymer-based sirolimus-eluting stent.

TCT-22

ABSORB Cohort B Trial: 18 Month Clinical and MSCT Results of the ABSORB Bioresorbable Everolimus Eluting Vascular Scaffold

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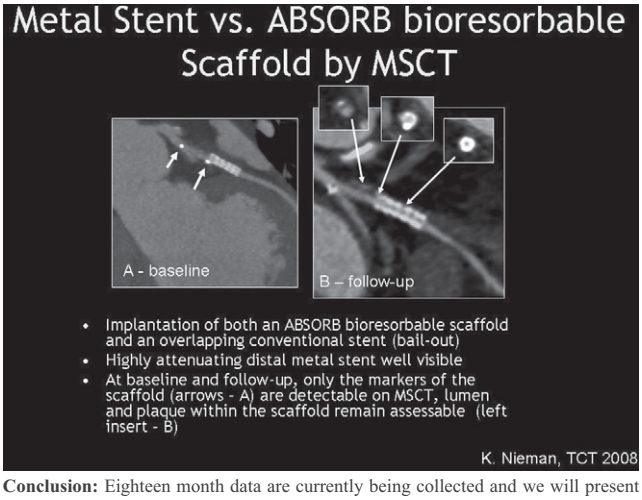
Background: Multislice computed tomography (MSCT) coronary angiography has emerged as a non-invasive diagnostic modality to evaluate coronary artery disease. However, visualization or evaluation of the in-stent lumen by MSCT is challenging owing to the blooming artefact caused by metallic stent struts. The feasibility and accuracy of the use of MSCT in the analysis of radiolucent bioresorbable scaffolds could indicate a new era for non-invasive assessment of patients treated with radiolucent devices.
Methods: The ABSORB Cohort B trial enrolled 101 patients at 12 sites in the European and Asia Pacific regions between March and November 2009. The current aim is to assess, by MSCT, the midterm results at 18 months in terms of patency and absence of binary restenosis of the ABSORB bioresorbable everolimus eluting vascular scaffold (Abbott Vascular, Santa Clara, CA, USA).
Results: In the smaller ABSORB Cohort A study, we have previously demonstrated that non-invasive imaging of the ABSORB scaffold patency with MSCT is feasible without the artifacts associated with conventional metal stents. In the ABSORB Cohort B trial, clinical data up to 1 year for the full cohort of 101 patients are currently available. In these 101 patients, 1 year results showed an ID-MACE rate of 6.9%. The 18-month clinical and MSCT results for the full cohort of 101 patients from the ABSORB Cohort B trial will be presented.



Conclusion: Eighteen month data are currently being collected and we will present 18-month clinical and MSCT results for the full cohort of patients from the ABSORB Cohort B trial.

TCT-23

Drug-Eluting Stents with Biodegradable Polymer: Do They Offer Benefit in the Treatment of Very Small Vessels (<2.5mm)

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Background: Very small coronary vessels (reference diameter <2.5mm) are often associated with diabetic and female patients and remain an important challenge in interventional cardiology. We studied a large population of patients with very small vessels treated with Nobori DES coated only abluminally with a matrix of biolimus A9 and a biodegradable polymer.
Methods: We studied 1284 patients with at least one lesion located in a very small vessel (SV) treated with Nobori stent. The primary endpoint of the study is target lesion failure (TLF) defined as cardiac death, target vessel related myocardial infarction (MI) and target lesion revascularization (TLR). Data are captured electronically with an extensive monitoring (100% on-line and 30% on-site). An independent clinical event committee adjudicated all adverse events and an independent corelab analyzes baseline and adverse events angiograms.
Results: Patients were 65±11 years old, 23% were female, 34.8% had undergone previous PCI treatment, 52.1% were admitted with acute coronary syndrome, 32.6% were diabetic (7.6% insulin dependent) and more than 70% were hyperlipidemic and hypertensive. A mean number of 1.96±1.18 stents were implanted per patient, with 1.67±0.86 lesions per patient treated. Direct stenting was performed in 27.7% of the procedures and femoral access site was used in 61% of the patients. A total of 69% of the lesions were complex (type B2+C), 26.4% calcified, 20.0% bifurcated, 10.6% ostial and 6.3% presented ulceration. By QCA the mean RVD was 2.29±0.48mm. At 2 years, 94.7% of the patients were available for follow-up with reported TLF rate of 3.7% and stent thrombosis rate of 0.8%.
Conclusion: Although very small vessels are considered challenging to treat and represent a higher risk for adverse outcomes, this analysis showed very low rates of TLF and stent thrombosis up to 2 years, indicating excellent efficacy and safety of the Nobori stent in the treatment of very small vessels.

TCT-25

Bioresorbable Everolimus Eluting Vascular Scaffold in Small Vessels One year results

Roberto Diletti[1], Hector M Garcia-Garcia[14], Vasim Farooq[1], Yoshinobu Onuma[1], Salvatore Brugaletta[1], Robert Jan van Geuns[1], Evelyn Regar[1], Bernard de Bruyne[2], Dariusz Dudek[3], Leif Thuesen[4], Bernard Chevalier[5], Dougal McClean[6], Stephan Windecker[7], Robert Whitbourn[9], Pieter Smits[8], Jacques Koolen[10], Ian Meredith[11], Xiaolin Li[13], Dong Li[12], Susan Veldhof[12], Richard Rapoza[13], John A Ormiston[15], Patrick Serruys[1]
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Background: The second generation Bioresorbable Everolimus Eluting Vascular Scaffolds (BVS) are untested at the mid-term follow-up in the subset of small coronary vessels. We investigated the performance of the second generation BVS (Abbott Vascular, Santa Clara, CA) in small coronary arteries (<2.5mm) at 1-year follow-up
Methods: The ABSORB Cohort B Trial is a multicentre single-arm, prospective, open-label trial enrolling 101 patients. In the present post-hoc analysis, the study population was sorted according to the pre-procedural reference vessel diameter (RVD) into two groups: 1) Small-vessel group with RVD <2.5mm (41 patients, 41 lesions) and 2) Large-vessel group with RVD >=2.5 mm (60 patients, 61 lesions). Clinical outcomes were assessed at one-year follow-up for the entire population and compared between the two groups. Out of the total population 45 patients were assigned to undergo 6-month coronary angiography and 56 patients (57 lesions) to have the procedure performed at one year.
Results: At one-year after implantation no differences in Ischemia-Driven (ID) Major Adverse Cardiovascular Events (small vessels 3/41 cases, 7.3% vs. large vessels 4/60 cases, 6.7%,p=1.0000), Myocardial Infarction (small vessels 2/41 cases, 4.9% vs large vessels 1/60 case, 1.7%,p=0.5645) and ID-Target Lesion Revascularization (small vessels 1/41 case, 2.4% vs large vessels 3/60 cases, 5.0%, p=0.6445) were reported

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